Remarks

Prior to this amendment, claims 1-42 were pending in this application. New claim 43 is added. Claims 1, 4, 11-20, and 40-42 are amended herein. Claim 4 is amended to correct matters of form. After entry of this amendment, claims 1-43 are pending in this application.

Support for the amendment of claims 1, 11-20, and 40-42 can be found in the specification, for instance in the sequence listing. Support for new claim 42 can be found in the specification at page 44, line 22 through page 46, line 5.

Applicant expressly reserves the right to pursue protection of any or all subject matter removed by the current amendment in a subsequent application. No new matter has been added by these amendments.

Telephone Interview

Applicant thanks Examiner Halvorson for the courtesy of telephone interviews with their representative, Dr. Anne Carlson, on October 16, 2006, and on November 2, 2006. During the interviews, the species election was discussed. Applicant thanks Examiner Halvorson for clarifying that Groups 10 (claim 35) and 11 (claim 36), and not Groups 9 and 10, are subject to a species election of one of the tumors recited in claim 29. Applicant also thanks the Examiner for pointing out that amino acid residues 241-356, as recited in the original claims, are outside of the p28ING5 protein (which consists of amino acid residues 1-240). The claims have been amended to identify the residues at the 3' end of the protein (amino acid residues 226-240).

Response to Restriction Requirement

Claims 1-42 of this §371 National Stage application were indicated as being subject to a restriction requirement (finding of lack of unity). In particular, the following Groups have been designated:

Group 1	Claims 1-2 drawn to a tumor suppressor protein;
Group 2	Claims 3-9, 11-19 and 40-42 drawn to an oligonucleotide;
Group 3	Claim 10 drawn to a transgenic animal;

Group 4	Claims 20-21 drawn to a method of inhibiting cellular proliferations comprising transfecting a cell;
Group 5	Claims 22-23 drawn to a method of inhibiting cellular proliferation comprising contacting a cell with the protein;
Group 6	Claims 24-25 drawn to a method of enhancing cellular proliferation comprising transfecting a cell;
Group 7	Claim 26 drawn to a specific binding agent;
Group 8	Claim 27 drawn to a method of screening for an agent that modulates tumor suppressor activity;
Group 9	Claim 28 drawn to a method of detecting a tumor suppressor protein in a biological sample;
Group 10	Claim 35 drawn to a method of diagnosing the presence of a tumor comprising amplifying the nucleotide of SEQ ID NO:1;
Group 11	Claim 36 drawn to a method of diagnosing a tumor in a subject comprising identifying a mutation;
Group 12	Claim 37 drawn to a method of treating a neoplasm;
Group 13	Claim 38 drawn to a kit comprising an antibody specific or p28ING5 protein;
Group 14	Claim 39 drawn to a kit comprising an amplification primer that specifically amplifies the nucleic acid that encodes the p28ING5 protein.

The Office action states that "Groups 1-14 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features…" All of the Groups do in fact relate to a single special technical feature, which feature makes a contribution over the prior art. As such, all of the claims should be examined together. Applicant requests that the requirement be withdrawn in light of the arguments and amendments herein.

Standard for Analyzing Unity of Invention

37 CFR § 1.475 requires unity of invention in a national stage application such as this; unity of invention is present when a group of inventions are "so linked as to form a single general inventive concept." [*See* 37 CFR § 1.475(a).] "A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature." [MPEP § 1893.03(d). *See also* 37 CFR § 1.475(a).]

Further, "The expression 'special technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." [*See* 37 CFR § 1.475(a), emphasis added.]

This makes it clear that an analysis with regard to unity of invention occurs in two stages. First, is there a special technical feature shared among the claims/groups of inventions, such that they are linked to form a single inventive concept? If there is, then one asks does that special technical feature **define a contribution over the prior art** for each of the claimed inventions? If no relevant prior art is identified, then there can be no finding of lack of unity.

Applying the Standard in the Current Case

At least Groups 1 through 12 are linked to form a single general inventive concept. Upon a review of the application and the claims, it is clear that the invention as claimed relates to a "purified p28ING5 tumor suppressor protein having a sequence comprising amino acid residues 1-13 **and** 226-240 of SEQ ID NO: 2" (amended claim 1; emphasis added). Claims 2-37 and 40-42 (Groups 1-12) depend, directly or indirectly, from amended claim 1 and incorporate all of the limitations thereof. Thus, at a minimum, claims 1-37 and 40-42 all relate to a protein comprising amino acid residues 1-13 and 226-240 of SEQ ID NO: 2.

The Office action states that the "technical feature linking Groups 1-14 appears to be that they all relate to a tumor suppressor protein, p28ING5, comprising **amino acid residues 1-13 of SEQ ID NO:2**" and that "Marcu (U.S. Patent No:6,066,474, issued May 23, 2000) describes an IKK binding protein comprising amino acid residues 1-14 of SEQ ID NO: 1 of the present application (see sequence search). Thus, Marcu's protein reads on the instant applicant's p28ING5 protein comprising amino acids 1-14" (see page 4; emphasis added). Applicant disagrees.

First, Applicant notes that the sequence search provided with the Office action demonstrates that Marcu discloses an IKK binding protein comprising amino acid residues 1-**13** of SEQ ID NO: 1 of the present application (not 1-14 of SEQ ID NO: 1, as suggested in the Office action). Second, claim 1 as amended requires more than amino acid residues 1-13 of SEQ ID NO: 2; *both* amino acid residues 1-13 **and** 226-240 of SEQ ID NO: 2 are required. Thus, the special technical feature linking claims 1-37 and 40-42 is a tumor suppressor protein comprising amino acid residues 1-13 **and** 226-240 of SEQ ID NO: 2, which is *explicitly* recited in claims 1-

37 and 40-42 (that is, independent claim 1, as amended, and all the claims that depend therefrom). As Marcu does not disclose amino acid residues 226-240 of SEQ ID NO: 2, Marcu does not anticipate current claim 1. Thus, this special technical feature does define a contribution over the prior art for each of the claimed inventions in the group of inventions. This feature is a basis for patentability of Applicant's invention.

In summary, **as required by 37 CFR § 1.475**, the claims at least of Groups 1-12 have unity of invention because they are directed "to a group of inventions so linked as to form a single general inventive concept" because "there is a technical relationship among [the] inventions involving one . . . corresponding technical feature[]" – **amino acid residues 1-13 and 226-240 of SEQ ID NO: 2** – and this special technical feature "define[s] a contribution . . . over the prior art."

Since unity of invention exists among Groups 1-12 in the present application, it is inappropriate to subject claims 1-37 and 40-42 to a requirement for restriction. Applicant requests that the requirement be withdrawn, that Groups 1-12 be rejoined, and that the corresponding claims be examined in the current case.

Election

Under protest, and only to comply with 37 CFR §1.499, Applicant hereby provisionally elects Examiner's Group 1 (corresponding to claims 1-2, directed to a tumor suppressor protein). Applicant expressly requests that the method claims, which depend from or otherwise include all the limitations of claims directed to the tumor suppressor protein, be rejoined and the claims examined, at the latest upon the allowance of any of the product claims. It is believed that this is in accordance with the current Patent and Trademark Office Guidelines for Restriction Requirements in TC1600.

In accord with 37 CFR §1.143, Applicant specifically reserves the right to petition to have the appropriateness of the finding of lack of unity/restriction requirement reconsidered, if it is maintained in spite of this response.

Conclusion

It is believed that the application is in condition for substantive examination. If any minor matters remain to be addressed prior to examination, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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